REMARKS

Claims 1-2 and 4-47 are currently pending in the present application. The claims have been amended to address several clerical issues throughout.

No new matter within the meaning of 35 U.S.C. §132 has been added. Therefore, entry of the amendment is respectfully requested.

1. Restriction / Election Requirement

The Official Action states that claims 1-2 and 4-47 are subject to an Restriction/ Election requirement.

As the basis of this rejection, the Official Action states, in relevant part:

> Restriction is required under 35 U.S.C. 121 and 372.
>
> This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
>
> In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.
>
> Group I, claim(s) 1, 2, 4-10, 21-32 and 45-47, drawn to an administration form for acid-labile active compounds comprising pharmaceutical excipients and multiple individual active compound units, classified in class 424, subclass 484.
>
> Group II, claim(s) 11-15, 18-20 and 33-44, drawn to an active compound unit comprising an acid-labile active compound (no pharmaceutical excipient) and a process for the production of an active compound unit in the form of a microsphere classified in class 424, subclass 489.

Group III, claim(s) 16 and 17, drawn to a process for the production of an active compound unit in the form of a microsphere comprising an acid-labile active compound, classified in class 424, subclass 489.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions of Groups I-III are drawn to distinct formulations and methods that contain different components and features.

Election

Applicants elect Group II with traverse.

Traversal

Applicants respectfully traverse this restriction/election requirement because each of the "Groups" of claims that the Examiner alleges are "unrelated" share a special technical feature under PCT Rule 13.2. Accordingly, all of the presently pending claims possess unity of invention and restriction, therefore, is improper.

Unity of Invention between Groups I and II

Applicants respectfully submit that the claims of Group I and the claims of Group II possess "unity of invention" because they share a special technical feature as required by PCT Rule 13.2.

PCT Rule 13.2 states the following, in relevant part:

> "[T]he requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

In the present application, the special technical feature that is shared between Group I, the "administration form" claims, and Group II, the "active compound unit" claims, is the "active compound unit" itself. Applicants respectfully point out to the Examiner that the administration form comprises 1) the "active compound unit" and 2) a pharmaceutical excipient. Thus, the difference between the claims contained in Group I and Group II is the presence of a pharmaceutical excipient.

In this regard, applicants note the Examiner's statement on page 3 of the Official Action:

> "[t]he invention of Group I requires the incorporation of pharmaceutical excipients, whereas the invention of Group II does not require excipients. Therefore, Groups I and II have different issues regarding patentability and enablement. The different inventions would require completely different searches in both patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden on the Examiner."

The mere presence of a pharmaceutical excipient is an improper basis for requiring restriction between a group of claims. In fact, the MPEP specifically outlines that unity of invention exists

in this situation. In particular, unity of invention between the claims contained in Groups I and II is clearly demonstrated by Annex B, Part 2 of the MPEP. This annex outlines particular examples and demonstrates when unity of invention is (or is not) present. Particular reference is made to Example 15 which demonstrates unity of invention between the following:

> "Claim 1: Compound A.
>
> Claim 2: An insecticide composition comprising compound A and a carrier.
>
> Unity exists between claims 1 and 2. The special technical feature common to all the claims is compound A."

As such, the mere presence of a pharmaceutical excipient (or 'a carrier' in Example 15) is clearly an improper basis for requiring restriction between groups of claims. If the presence of a carrier were a proper basis for restriction, an applicant could not obtain claims to a novel compound and claims to a pharmaceutical composition comprising that novel compound and a carrier in the same patent. Such is not the law of unity of invention because the compound claims and the composition claims share a "special technical feature", i.e. the novel compound itself.

Applicants further point out to the Examiner that MPEP 1850 states the following, in relevant part:

> "[I]t is clear that the decision with respect to unity of invention rests with the International Searching Authority or the International Preliminary Examining Authority. However, the International Searching Authority or the International Preliminary Examining Authority should not raise objection of lack of unity of invention merely because the inventions claimed are classified in separate classification groups or merely for the purpose of restricting the international search to certain classification groups."

In this regard, applicants respectfully note that the International Preliminary Examination Report does not contain an indication of "Lack of unity of invention" between the claims of the underlying PCT application which were substantially similar to the claims presently pending in this application.

For these reasons, unity of invention clearly exists between Groups I and II because the special technical feature common to all of the claims is the "active compound unit".

Unity of Invention between Groups I and III and Groups II and III

Likewise, unity of invention exists between Groups I and III and between Groups II and III. As outlined above, the special technical feature common to the claims in Groups I and II (i.e. the "active compound unit") is also present in the claims of Group III (claims 16 and 17).

Accordingly, the claims of Groups I, II and III all possess unity of invention because they all share the special technical

feature of an "active compound unit". The Examiner is therefore respectfully requested to reconsider and withdraw the restriction / election requirement of claims 1-2 and 4-47.

CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the restriction / election requirement of pending claims 1-2 and 4-47. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,

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Appendix A

Claim Amendments

1. (Currently amended) An administration form for acid-labile active compounds, comprising pharmaceutical excipients and multiple individual active compound units,

wherein the acid-labile active compound is selected from the group consisting of an acid-labile ~~active~~ proton pump inhibitor, a salt of an acid-labile proton pump inhibitor with a base, and a hydrate of a salt of an acid-labile proton pump inhibitor with a base, and is present in the individual active compound units in a matrix made of a mixture comprising at least one fatty alcohol and at least one solid paraffin, and wherein said individual active compound units are microspheres.

2. (Currently amended) An administration form for acid-labile active compounds, comprising pharmaceutical excipients and multiple individual active compound units, wherein the acid-labile active compound is selected from the group consisting of an acid-labile proton pump inhibitor, a salt of an acid-labile proton pump inhibitor with a base, and a hydrate of a salt of an acid-labile proton pump inhibitor with a base, and

is present in the individual active compound units in a matrix made of a mixture comprising at least one triglyceride and at least one solid paraffin or in a matrix made of a mixture comprising at least one fatty acid ester and at least one solid paraffin, wherein said individual active compound units are microspheres.

3. (Canceled)

4. (Previously presented) The administration form as claimed in claim 1, wherein the active compound present is an acid-labile proton pump inhibitor.

5. (Original) The administration form as claimed in claim 4, wherein the acid-labile proton pump inhibitor present is pantoprazole.

6. (Previously presented) The administration form as claimed in claim 1, wherein, in the mixture, one or more further excipients, selected from the group consisting of polymers, sterols and basic compounds, is/are present in the individual active compound units.

7. (Currently amended) The administration form as claimed in claim 6, wherein the polymer is selected from the group consisting of povidone, vinylpyrrolidone/vinyl acetate copolymer, polyvinyl acetate, cellulose ethers, cellulose esters, methacrylic acid/methyl methacrylate copolymer, [[or]] methacrylic acid/ethyl methacrylate copolymer and ~~or wherein the polymer is~~ mixtures thereof.

8. (Currently amended) The administration form as claim in claim 6, wherein the sterol is selected from the group consisting of ergosterol, stigmasterol, sitosterol, brassicasterol, campesterol, cholesterol, [[and]] lanosterol and ~~or wherein the sterol is~~ mixtures thereof.

9. (Previously presented) The administration form as claimed in claim 6, wherein the basic compounds are inorganic basic salts, amines or fatty amines.

10. (Currently amended) The administration form as claimed in claim 1, ~~which consists~~ selected from the group consisting of suspensions, gels, tablets, coated tablets, multicomponent tablets, effervescent tablets, rapidly disintegrating tablets,

powders in sachets, sugar-coated tablets, capsules and [[or]] suppositories.

11. (Currently amended) An active compound unit comprising an acid-labile active compound, wherein the acid-labile active compound in the active compound unit is selected from the group consisting of an acid-labile ~~active~~ proton pump inhibitor, a salt of an acid-labile proton pump inhibitor with a base, and a hydrate of a salt of an acid-labile proton pump inhibitor with a base, and is present in a matrix made of a mixture comprising at least one fatty alcohol and at least one solid paraffin, wherein said active compound unit is a microsphere.

12. (Currently amended) An active compound unit comprising an acid-labile active compound, wherein the acid-labile active compound in the active compound unit is selected from the group consisting of an acid-labile proton pump inhibitor, a salt of an acid-labile proton pump inhibitor with a base, and a hydrate of a salt of an acid-labile proton pump inhibitor with a base, and is present in a matrix made of a mixture comprising at least one fatty acid ester and at least one solid paraffin or in a matrix made of a mixture comprising at

least one triglyceride and at least one solid paraffin, wherein said active compound unit is a microsphere.

13. (Currently amended) The active compound unit as claimed in claim 11, wherein one or more further excipients[[,]] selected from the group consisting of polymers, sterols and basic compounds, is/are present in the matrix.

14. (Previously presented) The active compound unit as claimed in claim 11, wherein the active compound present is an acid-labile proton pump inhibitor.

15. (Previously presented) The active compound unit as claimed in claim 11, wherein the microsphere has a particle size range of 50-800 µm.

16. (Currently amended) A process for the production of an active compound unit in the form of a microsphere comprising an acid-labile active compound, where the acid-labile active compound is selected from the group consisting of an acid-labile proton pump inhibitor, a salt of an acid-labile proton pump inhibitor with a base, and a hydrate of a salt of an acid-labile proton pump inhibitor with a base, and is present

in the microsphere in a matrix comprising at least one fatty alcohol, comprising producing drops of a solution or dispersion of the acid-labile active compound in at least one fatty alcohol by means of vibrating nozzles and solidifying the drops formed in a suitable medium.

17. (Previously presented) A microsphere prepared by the process as claimed in claim 16.

18. (Currently amended) A process for the production of an active compound unit in the form of a microsphere comprising an acid-labile active compound, where the acid-labile active compound is selected from the group consisting of an acid-labile proton pump inhibitor, a salt of an acid-labile proton pump inhibitor with a base, and a hydrate of a salt of an acid-labile proton pump inhibitor with a base, and is present in the microsphere in a matrix made of a mixture comprising at least one fatty alcohol and at least one solid paraffin, at least one triglyceride and at least one solid paraffin or at least one fatty acid ester with at least one solid paraffin, comprising the following steps:

a. preparing a solution or dispersion of the acid-labile active compound in the fatty alcohol and paraffin,

triglyceride and paraffin or fatty acid ester and paraffin;

b. prilling the ~~liquid phase from~~ solution or dispersion prepared in step (a) and obtaining drops of the solution or dispersion; and

c. solidifying the drops ~~formed~~ obtained in step (b) in a suitable medium.

19. (Currently amended) The process as claimed in claim 18, where the prilling is carried out by means of vibrating nozzles, ~~the liquid phase flowing~~ wherein the solution or dispersion which flows to the nozzle ~~being~~ is kept at a constant temperature, and wherein the solidification of the drops ~~taking~~ takes place in a suitable cooling medium after stabilization thereof by sudden quenching.

20. (Previously presented) A microsphere prepared by the process as claimed in claim 18.

21. (Currently amended) The administration form as claimed in claim 1, wherein the acid-labile proton pump inhibitor is selected from the group consisting of omeprazole, pantoprazole, lansoprazole and rabeprazole.

22. (Currently amended) The administration form as claimed in claim 1, wherein the acid-labile proton pump inhibitor is pantoprazole sodium sesquihydrate, (-)-pantoprazole sodium sesquihydrate, omeprazole magnesium, omeprazole, esomeprazole magnesium or esomeprazole.

23. (Currently amended) The administration form as claimed in claim 1, wherein the acid-labile proton pump inhibitor is pure enantiomer.

24. (Currently amended) The administration form as claimed in claim 1, wherein the acid-labile proton pump inhibitor is esomeprazole or (-)-pantoprazole.

25. (Currently amended) The administration form as claimed in claim 1 **[[3]]**, wherein the microspheres have a particle size range of 50-500 µm.

26. (Currently amended) The administration form as claimed in claim 1 **[[3]]**, wherein the microspheres have a particle size range of 50-400 µm.

27. (Previously presented) The administration form as claimed in claim 26, wherein the microspheres are monomodal microspheres.

28. (Previously presented) The administration form as claimed in claim 27, wherein the microspheres have a particle size range of 50-200 µm.

29. (Previously presented) The administration form as claimed in claim 1, wherein the fatty alcohol is selected from the group consisting of cetyl alcohol, myristyl alcohol, lauryl alcohol, stearyl alcohol and mixtures thereof.

30. (Previously presented) The administration form as claimed in claim 2, wherein the triglyceride is selected from the group consisting of tristearate, tripalmitate, trimyristate and mixtures thereof.

31. (Previously presented) The administration form as claimed in claim 2, wherein the fatty acid ester is cetyl palmitate.

32. (Previously presented) The administration form as claimed in claim 1, wherein the solid paraffin is paraffinum solidum

or ozocerite.

33. (Currently amended) The active compound unit as claimed in claim 11, wherein the acid-labile proton pump inhibitor is selected from the group consisting of omeprazole, pantoprazole, lansoprazole and rabeprazole.

34. (Currently amended) The active compound unit as claimed in claim 11, wherein the acid-labile proton pump inhibitor is pantoprazole sodium sesquihydrate, (-)-pantoprazole sodium sesquihydrate, omeprazole magnesium, omeprazole, esomeprazole magnesium or esomeprazole.

35. (Currently amended) The active compound unit as claimed in claim 11, wherein the acid-labile proton pump inhibitor is pure enantiomer.

36. (Currently amended) The active compound unit as claimed in claim 11, wherein the acid-labile proton pump inhibitor is esomeprazole or (-)-pantoprazole.

37. (Previously presented) The active compound unit as claimed in claim 15, wherein the microsphere has a particle

size range of 50-500 µm.

38. (Previously presented) The active compound unit as claimed in claim 15, wherein the microsphere has a particle size range of 50-400 µm.

39. (Previously presented) The active compound unit as claimed in claim 38, wherein the microsphere is a monomodal microsphere.

40. (Previously presented) The active compound unit as claimed in claim 38, wherein the microsphere has a particle size range of 50-200 µm.

41. (Previously presented) The active compound unit as claimed in claim 11, wherein the fatty alcohol is selected from the group consisting of cetyl alcohol, myristyl alcohol, lauryl alcohol, stearyl alcohol and mixtures thereof.

42. (Previously presented) The active compound unit as claimed in claim 12, wherein the triglyceride is selected from the group consisting of tristearate, tripalmitate, trimyristate and mixtures thereof.

43. (Previously presented) The active compound unit as claimed in claim 12, wherein the fatty acid ester is cetyl palmitate.

44. (Previously presented) The active compound unit as claimed in claim 11, wherein the solid paraffin is paraffinum solidum or ozocerite.

45. (Previously presented) The administration form as claimed in claim 9, wherein the inorganic basic salts are selected from the group consisting of ammonium carbonate and sodium carbonate.

46. (Previously presented) The administration form as claimed in claim 9, wherein the amines are selected from the group consisting of meglumine, di- or triethylamine and TRIS (2-amino-2-hydroxymethyl-1,3-propandiol).

47. (Previously presented) The administration form as claimed in claim 9, wherein the fatty amine is stearylamine.